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### REMARKS

In the Office Action mailed January 13, 2006 (hereinafter referred to as "the instant Action"), claims 6-8 and 22-27 are listed as pending and all claims stand rejected. In response to the Instant Action, all pending have been amended. No claim has been canceled and no new claim has been added. Applicant declares that the above-requested amendments do not add new matter. Support for the amendment is found throughout the specification, e.g., at page 2, lines 9-15; page 7, line 8 to page 8, line 17; and Fig. 1.

Applicants respectfully reserve the right to either reintroduce canceled subject matter in the instant application at a later date in the prosecution in the event that the proposed amendments do not secure an allowance of the instant application and/or to file a subsequent application directed to said canceled matter.

Applicants are grateful for the withdrawal of the finality of the prior office action pursuant to 37 C.F.R. §1.114.

#### Claim Objections

1. Claim 24 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of the claim upon which it is dependent. In response thereto, Applicant has amended claim 24 to be dependent upon claim 22.

Applicant respectfully requests the reconsideration and withdrawal of the objection to claim 24 under 37 C.F.R. § 1.75(c).

#### Claim Rejections Under 35 U.S.C. § 112, second paragraph

2. Claims 6-8 and 22-27 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner is of the opinion that the terms "the [or "a] plunger" and "septum plunger"

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are vague and unclear. Although Applicant submits that one skilled in the art would not be confused since Applicant consistently refers to the septum plunger as "septum plunger" or "said septum plunger," in an effort to remove any possible ambiguity, Applicant has amended all pending claims to include the reference numerals corresponding to Figs. 1-23. Applicant avers that one skilled in the art would readily refer to the figures when reviewing the instant application and would, therefore, understand what features of the invention are referred to by "the plunger" and "the septum plunger". As such, claims 6-8 and 22-27, as amended, fulfill the requirements if 35 U.S.C.

§112, second paragraph.

With respect to the rejection of claim 25 as unclear due to the lack of antecedent basis for "the movement," Applicant has amended same to replace the offending term with language indicating that the claimed lock prevents the plunger "from sliding in the proximal end of the housing." Applicant notes that the plunger is arranged so as to "slide" in the proximal end of the housing according to claim 6 from which rejected claim 25 is dependent thereon.

Applicant respectfully request the reconsideration and withdrawal of the rejection of claims 6-8 and 22-27 under 35 U.S.C. § 112, second paragraph.

#### Obviousness-Type Double Patenting

3. Claims 6-8, 22-24 and 27 remain rejected as allegedly unpatentable over claim 1 of U.S. Patent No. 5,695,463 issued to Cherif-Cheikh (hereinafter "Cherif-Cheikh") in view of claims 1, 3 and 4 of U.S. Patent No. 2,460,039 issued to Scherer *et al.* (hereinafter "Scherer") under the judicially created doctrine of obviousness-type double patenting. Applicant respectfully traverses the rejection as to the currently amended claims.

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Applicant disagrees with the Office Action's assertion (at page 4) that claim 1 of Cherif-Cheikh "discloses the invention substantially as claimed." The device disclosed in claim 1 of Cherif-Cheikh (the "Cherif-Cheikh device") is significantly different from the device of the present invention. For example, prior to pushing the plunger of a claimed device, the drug composition is isolated from the needle by a septum plunger. The composition is exposed to the needle only upon piercing the septum plunger during injection.

Unlike the currently claimed device, the Cherif-Cheikh device does not include a septum plunger configured to isolate an injectable composition from the needle prior to pressing the plunger during injection. In fact, the Cherif-Cheikh device cannot use such a septum plunger, because it requires that the injectable composition be located inside the needle prior to injection.

To elaborate this point, Claim 1 of Cherif-Cheikh recites "a rod within said needle, said rod extending through said main body ...and affixed to said plunger" of the device..."wherein said plunger and rod are operative to push the medicament through said needle into said mammal, as the needle is being withdrawn from said mammal" (Cherif-Cheikh column 4, lines 6-8 and 17-20). Applicant also refers the Examiner to Figs. 1-4 of Cherif-Cheikh.<sup>1</sup> The Figures and specification clearly indicate that in the Cherif-Cheikh device, "a rod **16** is guided into needle **12** and abuts medicament **20** which is positioned in the needle **12**" (column 2, lines 50-51). In the Cherif-Cheikh device, pressing the plunger causes the rod, located within the needle, to push a medicament, which is also located within the needle, through said needle and into a mammal, thus, the prior art device is clearly different from the presently claimed device.

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<sup>1</sup> As stated in MPEP 804, 1, "those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." *Citing In re Vogel*, 422 F.2d 438, 441-42, (CCPA 1970).

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Applicant also submits that a person of skill in the art would not have been motivated to alter the Cherif-Cheikh device to isolate the composition from the needle because such a modification would render the prior art device unsuitable for its intended purpose. A composition isolated outside of the needle in the Cherif-Cheikh device could not be pushed from the housing into and through the needle, because the rod recited in Cherif-Cheikh (which is "inside said needle") would prevent the movement of the composition from the housing into the needle. The Applicant submits that adapting the Cherif-Cheikh device to the currently amended claims would require removing the rod recited by claim 1 in Cherif-Cheikh, however, the prior art provides no suggestion or motivation to remove this rod.

Furthermore, adapting the Cherif-Cheikh device to the currently amended claims would *change the principle of operation* explicitly recited by claim 1 of Cherif-Cheikh. The currently claimed device uses an increase of pressure within the housing caused by depressing the plunger to pierce a septum plunger and subsequently push a composition from the housing into the needle. On the other hand, claim 1 of Cherif-Cheikh requires that the rod be "operative to push medicament through the needle." In this regard, Applicant reminds the Office that if a "proposed modification would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the current claims *prima facie* obvious." MPEP 2143.01 *citing In re Ratti*, 270 F.2d 810 (CCPA 1959).

Scherer, the additional reference cited in the Office Action, is proffered for its teaching of "a syringe wherein the medicament is kept sterile until the syringe is put into use by providing a slidable piston which seals and contains the medicament prior to use and puncture by a rear end of a double ended needle." This disclosure does not make up for the aforementioned functional differences between the Cherif-Cheikh device and the currently claimed device. Applicant submits that a person of skill in the

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art would not have been motivated to modify the Cherif-Cheikh device to (i) eliminate the rod, (ii) abandon the operative principle of using a rod to push a composition through a needle, and (iii) add a septum plunger configured to isolate an (injectable) composition from the needle prior to injection *and* to effectuate the protective sleeve, such that, during injection, (iv) the needle pierces the septum plunger thus allowing the composition to be pushed into and through the needle and (v) the septum plunger causes the protective sleeve to function as intended.

The Examiner's opinion that the piston of the Scherer device could be incorporated into the Cherif-Cheikh device and be capable of contacting the sleeve so as to "cover the needle prior to injection, retract into the housing during injection and to cover the needle after injection" utilizes impermissible hindsight. The piston of Scherer device is slidably arranged merely to allow the fixed hollow needle to penetrate it during use thus allowing the previously isolated medicament to flow into said hollow needle and out to the patient. There is no suggestion that the Scherer piston is capable of moving anything, particularly a protective sleeve. In addition, contrary to the Examiner's opinion, the Scherer piston is not equivalent to a septum plunger. Applicant carefully selected a septum plunger which provides a partition which separates the chamber containing the liquid or semi-solid composition from the sleeve so that none of the liquid or semi-solid composition escapes during the movement of the septum plunger effecting the ability of the sleeve to function as intended. There is no indication that the Scherer piston is capable of maintaining its "seal" after moving.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The Examiner has not identified such a motivation. Applicant respectfully demands that the Examiner identify the portion of

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either Cherif-Cheikh or Scherer she relies on in her reasoning. Second, there must be a reasonable expectation of success. As argued previously, combining the rod in needle assembly of Cherif-Cheikh with the piston assembly of Scherer would result in an inoperative injection device and certainly not an injection device capable of protecting the delivery needle before, during and after injection as well as maintaining the sterility of the medicament before, during and after administration thereof. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicant respectfully submits that neither Cherif-Cheikh nor Scherer teach a *septum* plunger capable of activating a protective sleeve. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In view of the current amendments, Applicant submits that the cited references do not establish a *prima facie* case of obviousness. Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 6-8 and 22-24 and 27 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of U.S. Patent No. 5,695,463 in the name of Cherif-Cheikh in view of U.S. Patent No. 2,460,039 in the name of Scherer *et al.*

4. Claim 25 stands rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly unpatentable over claim 1 of U.S. Patent No. 5,695,463 issued in the name of Cherif-Cheikh (hereinafter "Cherif-Cheikh") patent in view of U.S. Patent No. 2,460,039 issued in the name of Scherer *et al.* (hereinafter "Scherer") and U.S. Patent No. 5,399,170 issued in the name of Whitley (hereinafter "Whitley"). Applicant respectfully traverses the rejection.

As explained in detail above, Cherif-Cheikh, either alone or in combination with Scherer, does not disclose the invention of the currently amended claims. Whitley is

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cited as describing a releasable lock to prevent movement of the plunger prior to use, however, Whitley does not make up for the differences between Cherif-Cheikh in combination with Scherer and the presently claimed invention. Even when combined, these three references do not suggest or provide a motivation to (i) remove the rod limitation, (ii) add a septum plunger to the housing to isolate an injectable composition in a portion external to the needle, and (iii) add a septum plunger configured to isolate an (injectable) composition from the needle prior to injection *and* to effectuate the protective sleeve, such that, during injection, (iv) the needle pierces the septum plunger thus allowing the composition to be pushed into and through the needle and (v) the septum plunger causes the protective sleeve to function as intended. The Examiner has failed to establish a *prima facie* case of obviousness against amended claim 25.

Additionally, Whitley does not appear to disclose a releasable lock that prevents movement of the plunger into the housing as recited by claim 25. Whitley discloses a pair of "safety locks" 15 and a pair of stops 23 that, when engaged, prevent further movement of the plunger 9 into the inner sheath 4 of the device, however, even when engaged, these locks 15 do not prevent the plunger 9 from moving into the outer sheath 3, until inner sheath shoulders 16 engage outer sheath shoulders 17. Figures 11 and 12 in Whitney show that even with "safety locks" 215 and stops 223 engaged, the plunger 209 continues to move into the outer sheath 203 until the inner sheath shoulder (not numbered) and outer sheath shoulder (not numbered) are engaged. Thus, the "safety locks" disclosed in Whitley are not configured to prevent a plunger from moving into the housing, and do not meet the recited limitations of claim 25. The Office Action does not account for this difference between the current claims and the Whitley disclosure, nor does the rejection provide a suggestion or motivation to modify the Whitley mechanism (that prevents plunger movement into an inner sheath, but appears to allow

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plunger movement into an outer sheath) to arrive at the currently claimed releasable lock that prevents plunger movement into a syringe housing.

For the reasons presented above, Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,695,463 in the name of Cherif-Cheikh in view of U.S. Patent No. 2,460,039 in the name of Scherer *et al.* and in further view of U.S. Patent No. 5,399,170 in the name of Whitley.

5. Claim 26 stands rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly unpatentable over claim 1 of U.S. Patent No. 5,695,463 issued in the name of Cherif-Cheikh (hereinafter "Cherif-Cheikh") patent in view of U.S. Patent No. 2,460,039 issued in the name of Scherer *et al.* (hereinafter "Scherer") and U.S. Patent No. 5,242,416 issued in the name of Hutson (hereinafter "Hutson"). Applicant respectfully traverses the rejection.

As explained in detail above, Cherif-Cheikh, either alone or in combination with Scherer, does not disclose the invention of the currently amended claims. Hutson, which is cited for allegedly disclosing a retractable sleeve and a cap, does not make up for the deficiencies noted above in Cherif-Cheikh alone or in combination with Scherer. Even if a skilled artisan were to combine the cap disclosed in Hutson with a combination of the teachings of Cherif-Cheikh and Scherer, the combined disclosures would fail to teach or suggest a device with all of the currently recited claim elements. Absent such a teaching or suggestion, the office has failed to establish a *prima facie* case of obviousness.

For the reasons presented above, Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 26 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of



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U.S. Patent No. 5,695,463 in the name of Cherif-Cheikh in view of U.S. Patent No. 2,460,039 in the name of Scherer *et al.* and in further view of U.S. Patent No. 5,242,416 in the name of Hutson.

6. Applicant is grateful for the Examiner's reconsideration of the Tischlinger reference.

Applicant acknowledges the Examiner maintaining the finality of the previous Office Action for the reasons set forth on page 8 of the instant Action.

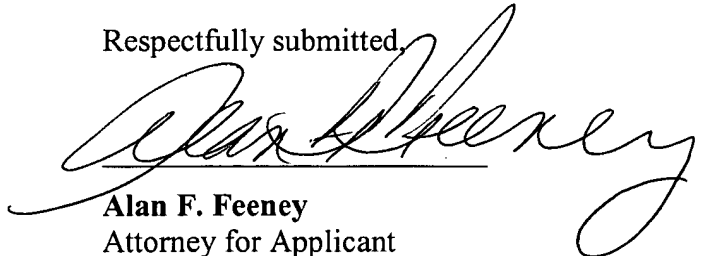
#### CONCLUSION

Applicant respectfully submits that the claims are in a condition for allowance and notification to that effect is respectfully requested. Examiner Lam is invited to telephone the Applicant's attorney at (508) 478-0144 to facilitate prosecution of this application.

Please apply any charges or credits to Deposit Account No. 50-0590 referencing attorney docket number 023B.

Date: 8-23-2006

Respectfully submitted,



**Alan F. Feeney**  
Attorney for Applicant  
Reg. No. 43,609

IPSEN (BIOMEASURE)  
27 Maple Street  
Milford, MA 01757-3650  
(508) 478-0144 telephone  
(508) 478-2530 facsimile  
alan.feeney@ipsen.com